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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,491	05/30/2000	Kurt Hertogs	07691.0009	8312

27777 7590 12/23/2002  
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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/580,491

Applicant(s)

Hertogs et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 4, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### DETAILED ACTION

The Examiner of record has changed. Please address all further correspondence to Examiner M. Borin, AU 1631.

Upon re-consideration of the issues in the case, withdrawal of rejection under 35 U.S.C. 103(a), and a new grounds of rejections were deemed necessary. Consequently, finality of the previous Office action is withdrawn. Applicants arguments with respect to rejection made under 35 U.S.C. 103 have been considered but are deemed moot in view of the new grounds of rejection. The following rejections constitute the complete set presently being applied to the instant application.

Claim 7 is the only claim pending. Pursuant to election of species, the mutations under consideration is at least one selected from 103S, 118I, and 88T, selected for (a), (b), and © in claim 7, respectively. Inasmuch as the election of species requirement requested election of a single mutation<sup>1</sup>, and the previous prosecution addressed, specifically, the mutation 88T, the said mutation is addressed herein as the elected species. Other species will be addressed upon acknowledgment

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<sup>1</sup>Note that the claim is drawn to "at least one nucleic acid ", i.e., to at least one mutant.

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of allowability of the method as drawn to the elected species. Thus, the instant Office action address the claimed method to the extent it reads on the mutation 88T.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by Condra et al.

The reference evaluates effectiveness of antiviral therapy of HIV patients with protease inhibitor Indinavir (IDV). To evaluate the effectiveness of therapy with IDV, blood of HIV infected patients was collected (same step as step I) of the instant claim), and nucleic acids encoding HIV protease are examined (i.e., as in step (ii)(c) of claim 7. In one patient, patient "O" at least one mutation, namely 88T (i.e., the elected species) correlates with reduced effectiveness of antiviral therapy (see table 1, patient "O") - the resistance to IDV increased to over 3000 nM (see table 1, column IDV CIC and p. 8270, right col., lines 9-10 from bottom). The thus identified at least one mutation correlates with reduced effectiveness of IDV (which reads on step (iii) of the instant claim.

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It is the Examiners position that all the elements of Applicant's invention with respect to the method of claim 7 are instantly disclosed by the teaching of the reference cited above.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim, to the extent it is drawn to the elected species, mutation 88T, is drawn to method of evaluating antiviral therapy of an HIV-infected patient based on identification of mutation 88T in HIV protease.

The prior art teaches that a single residue mutation is not conclusively indicative of development of resistance to HIV therapy. Condra et al teach that the highly variable nature of the observed amino acid substitutions precludes the identification

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of simple, invariant rules diagnostic for HIV resistance, no preferred order of appearances of any particular substitution is evident, and that the emergence of phenotypic resistance correlated with the appearance of substitutions at various numbers of amino acid residues among at least 11 sites in HIV protease (rather than just one site as instantly claimed). "No single pattern of amino acid substitution in viral protease was required for the development of resistance to Indinavir. Rather, phenotypic resistance resulted from the combined effects of multiple, highly variable combinations of amino acid variations". See p. 8271, last paragraph; p. 8275, first two paragraphs.

Specification mentions that "mutation at 88T confers resistance to nelfinavir" (p. 25, line 7). However, said disclosure is made while discussing information presented in Table 1. Close examination of said Table does not reveal any mention of 88T mutation. Further, there is no working examples demonstrating correlation of 88T mutation to increase or decrease in sensitivity to nelfinavir treatment. Furthermore, even if such information had been presented, there is no information on the correlation of 88T mutation to modulate sensitivity to treatment with any medication other than nelfinavir. In addition, there is no information on whether said mutation correlates to increase or decrease in the effectiveness of the PI therapy.

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The second mention of 88T mutation is in Table 2b, which informs that this single mutation correlates to phenotypic PI resistance. There is no further information, however, as to resistance to what particular drug this mutation correlates, how this mutation correlates to the resistance (increases or decreases the resistance).

Therefore, in view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not make and/or use the invention with the claimed breadth without an undue amount of experimentation.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 19, 2002

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

